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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/23/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/693,555	KORNMAN ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,17-32,42-57 and 80-84* is/are pending in the application.

4a) Of the above claim(s) *17-32 and 42-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 80-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. This action is in response to Paper No. 12, filed October 4, 2002. Applicants amendments and arguments presented in the response of Paper No. 12 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

2. Applicant's election with traverse of group I, claims 1-8 and 80-84 in Paper No. 12 is acknowledged. Applicant states: "the Office Action has apparently continued to treat as legitimate and final the illegitimate action of invading the structure of several of the claims to remove *en masse* the larger part of the claimed invention by insisting that all but one of the sequences of the various primers (SEQ ID NO: 1-18) must be removed before a search can be conducted." Applicants state that the examiner has not provided any authority for such an "improper and draconian restriction requirement." However, the requirement for restricting nucleic acid sequences is clearly set forth in MPEP 803.04: "By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C.

121. Absent evidence to the contrary, each such nucleotide sequence is presumed to **represent an independent and distinct invention**, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et SEQ. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et SEQ. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, **up to ten** independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together. In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten. In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do

not cover independent and distinct inventions." Applicants response refers to a "demand" set forth in the previous office action. Applicants have clearly mischaracterized the office action. The previous office did not demand that Applicant make any type of statement. The office action merely restated the information as set forth above, that Applicants have the opportunity to convey on the record that the inventions (i.e, the nucleic acids of SEQ ID NO: 1-18) should be examined together based on evidence showing that these inventions are not independent and distinct.

Applicants further state that they "will treat any limitation of the claims to a single primer/SEQ ID NO. as a species election requirement." However, the record is clear that this is a restriction requirement and should **not** be construed as an election of species. A second sequence will NOT be examined if the elected species is found allowable.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-8 and 80-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for determining a pregnant woman's predisposition to having a low birth weight baby comprising detecting the presence of IL-1A (+4845) allele 2 or IL-1B (-511) allele 2 wherein the detection of IL-1A (+4845) allele 2 and IL-1B (-511) allele 2 is indicative of a predisposition to having a low birth weight baby, does not reasonably provide enablement for methods which determine a predisposition to any adverse pregnancy outcome or methods which determine an adverse pregnancy outcome by detecting allele in linkage disequilibrium to of IL-1A (+4845) allele 2 or IL-1B (-511) allele 2 or methods

which detect any allele of the 33221461 haplotype in linkage disequilibruim IL-1A (+4845) allele 2 or any allele of the 44112332 haplotype in linkage disequilibrium with IL-1B (-511) allele 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 1-8 are drawn to a method for determining whether a subject is predisposed to having an adverse pregnancy outcome by detecting the presence of an of IL-1A (+4845) allele 2 or IL-1B (-511) allele 2 or any allele of the 33221461 haplotype in linkage disequilibruim IL-1A (+4845) allele 2 or any allele of the 44112332 haplotype in linkage disequilibrium with IL-1B (-511) allele 2. Claims 80-82 are drawn to methods for determining an increased susceptibility to an adverse pregnancy outcome comprising detecting in a sample of fetal material the presence of an of IL-1A (+4845) allele 2 or IL-1B (-511) allele 2 or any allele of the 33221461 haplotype in linkage disequilibruim IL-1A (+4845) allele 2 or any allele of the 44112332 haplotype in linkage disequilibrium with IL-1B (-511) allele 2. Accordingly, the claims include detecting, for example, IL-1A (-889), IL-1RN (VNTR), IL-1B (+3953), the 222/223 marker of IL-1A the gz5/gz6 marker of IL-1A etc. Claims 83-84 are drawn to methods for predicting an increased susceptibility to adverse pregnancy outcome comprising determining a the genetic polymorphism pattern of a subject for any IL-1A or IL-1B allele and comparing the subject's pattern to a control sample's IL-1A allele 2 and IL-1B (TaqI) allele 2 pattern. The specification (page 63) teaches that "White women showed a trend towards association between individuals carrying at least 1

copy of allele 2 at +4845 and -511 and low birth weight with an odds ratio of 2.83 (95% CI 0.196-40.97). A significant association was demonstrated in black women carrying at least 1 copy of allele 2 +4845 with an odds ratio of 4.8 (95% CI 1.155-19.951, P=0.033) with low birth weight. Furthermore, a significant association between low birth weight and genotype was demonstrated in black women carrying at least 1 copy of allele 2 at each locus of +4845 plus -511 with an odds ratio of 8.89 (95% CI 1.934-40.855, P=0.0068)." Accordingly, the specification teaches an association in black and white women between the presence of both the IL-1A (+4845) allele 2 and IL-1B (-511) allele 2 and low birth weight. In black women an association was also identified between the presence of the IL-1A (+4845) allele 2 and low birth weight. No association is disclosed between the IL-1B (-511) allele 2 alone and the occurrence of low birth weight or between the IL-1A (+4845) allele 2 and low birth weight in white woman. Accordingly, the specification has not enabled methods which determine susceptibility to low birth weight by detecting the presence of the IL-1A (+4845) allele 2 alone in the general population or by detecting the IL-1B (-511) allele 2. The specification does not teach an association between low birth weight and any other IL-1A, IL-B or IL-1RN alleles. Furthermore, the specification has not taught an association between low birth weight and any alleles in linkage disequilibrium with IL-1A (+4845) allele 2 or IL-1B (-511) allele 2. The art has not established a correlation between any alleles of IL-1 and the occurrence of adverse pregnancy outcome which would allow for a general relationship to be established between the presence of an IL-1 gene cluster allele and any adverse pregnancy outcome. In particular, with respect to

claims 83-84, the specification provides no information regarding the frequency of the IL-1B (Taq; +3953) allele or additional IL-1A allele (other than IL-1A (+4845) and the occurrence of LBW or adverse pregnancy response. While the specification postulates that alleles in linkage disequilibrium with the stated interleukin alleles could also be used to diagnose adverse pregnancy outcome, given the fact that other alleles are not in 100% linkage disequilibrium with the stated alleles and that stated alleles have variable frequencies of association with low birth weight, it is highly unpredictable as to whether alleles in linkage disequilibrium with of IL-1A (+4845) allele 2 or IL-1B (-511) allele 2 or any other IL-1 allele would be sufficiently correlated with the occurrence of adverse pregnancy outcome or low birth weight. Further, while the specification suggests that IL-1 genotypes association with inflammation may be used to diagnose any disease that involves inflammation, Applicants have not provided sufficient evidence to establish that any level of inflammation or any inflammatory response in a pregnant women is correlated with adverse pregnancy outcome. Moreover, while the specification provides results regarding the frequency of IL-1A (+4845) allele 2 or IL-1B (-511) allele 2 and the adverse pregnancy outcome of low birth weight, the specification has not taught an association between these alleles and any other type of adverse pregnancy outcome. Adverse pregnancy outcome includes many types of distinct conditions, such as preterm labor, premature rupture of membranes, still-birth, ectopic pregnancy, and abdominal pregnancy. Applicants have not provided sufficient evidence to show that all adverse pregnancy outcomes are associated with inflammation and are correlated with the presence of any allele 2 IL-1 genotype. It would clearly

require extensive experimentation for one of skill in the art to analyze all other types of adverse pregnancy outcomes to identify additional outcomes that are correlated with the presence of a particular IL-1 genotype, particularly given the high level of unpredictability in the art of establishing a correlation between an allele and the occurrence of a condition and given the lack of sufficient guidance provided by the specification. Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation." *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification has identified only 2 alleles in two IL-1 genes out of all possible IL-1 genes and has disclosed the use of only these alleles together as a means for diagnosing a predisposition to LBW. Thereby, the scope of the claims does not bear a reasonable correlation to the scope of enablement provided by the specification and undue experimentation would be required to practice the full scope of the claims because this would require randomized searching of IL-1 genes for additional alleles which may be analyzed for their association with adverse pregnancy outcome. The specification has not provided any data regarding the frequency of additional IL-1 alleles (i.e., alleles other

than IL-1A (+4845) allele 2 or IL-1B (-511) allele 2) in other types of conditions associated with adverse pregnancy outcome and has not established a universal correlation between IL-1 polymorphisms and all types of adverse pregnancy outcomes. Moreover, with respect to claim 8, the broadest reasonable interpretation of this claim indicates that the claim is inclusive of methods which identify new alleles associated with low birth weight. While the specification is enabling for methods for detecting IL-1A (+4845) allele 2 and IL-1B (-511) allele 2 as indicative of an increase susceptibility to giving birth to a LBW baby, the specification is not enabling for methods which search for additional alleles that may be in linkage disequilibrium with IL-1A (+4845) allele 2 or IL-1B (-511) allele 2. It is unclear as to whether this claim is intended to be limited to general methods which detect any allele of the 33221461 haplotype in linkage disequilibruim IL-1A (+4845) allele 2 or any allele of the 44112332 haplotype in linkage disequilibrium with IL-1B (-511) allele 2 or whether the claim is intended to be limited to methods which detect members within the 33221461 haplotype in linkage disequilibruim IL-1A (+4845) allele 2 or members within the 44112332 haplotype in linkage disequilibrium with IL-1B (-511) allele 2, wherein some of the individual members are then identified as being associated with low birth weight (with the implication that not all members of these haplotypes are associated with low birth weight). To make and use an invention requires that the invention have a "real world" use. However, uses that require carrying out further research do not constitute a real world use. Thus, the specification has not adequately enabled methods which search for novel alleles associated with low birth weight. With respect to claims 80-82, the

specification does not teach the frequency of any IL-1 alleles in a fetus and the occurrence of adverse pregnancy outcome. There is no information regarding the genotype of a fetus and how this effects the birth weight of the fetus or any other conditions associated with adverse pregnancy outcome. No association has been established between the fetal genotype and the maternal genotype which would allow one to conclude that if a maternal genotype is associated with LBW or adverse pregnancy outcome, then the same fetal genotype would also be associated with LBW or adverse pregnancy outcome. Accordingly, in view of the lack of information in the specification as to how to reasonably identify other IL-1 alleles associated with low birth weight or adverse pregnancy outcome without undue experimentation and in view of the unpredictability in the art in correlating the presence of an allele with a specific condition, undue experimentation would be required for one of skill in the art to practice the invention as it is broadly claimed.

RESPONSE TO ARGUMENTS:

In the response filed October 4, 2002 Applicants state that the enablement of the claimed invention is not necessarily limited to any one particular working example. Applicants state that a "reasonable correlation" has been made and therefore applicants should be entitle to the full scope of the claims. These arguments have been fully considered but are not persuasive. Applicants have not elaborated as to why a showing of a correlation between 2 polymorphisms and the risk of a pregnant women having a low birth weight baby is "reasonably correlated" with and commensurate in scope with methods of determining whether any subject is predisposed to

having an adverse pregnancy outcome by detecting any allele of the 33221461 haplotype in linkage disequilibruim IL-1A (+4845) allele 2 or any allele of the 44112332 haplotype in linkage disequilibrium with IL-1B (-511) allele 2. Additionally, Applicants response does not indicate why the results obtained using samples obtained from a pregnant woman and used to determine whether that a pregnant women is likely to have a low birth weight baby could be extrapolated to samples obtained from a fetus. Why would such results obtained with a pregnant woman be reasonably correlated with the results obtained from a fetus? The response appears to imply that the rejection is based solely on the fact that Applicants have provided only one working example. However, the rejection as set forth above clearly is not based solely on the lack of working examples, but rather is based on the unpredictability in the art, the breadth of the claims and the level of experimentation that would be required to practice the invention as it is broadly claimed.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.d. 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Long*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.32 (c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 80-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,268,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '142 are both inclusive of methods for diagnosing a disease by detecting the presence of IL-1A (+4845) allele 2 or IL-1B (-511) allele 2. The instant claims are limited to methods for diagnosing adverse pregnancy outcome including preterm labor and low birth weight. The claims of '142 are inclusive of methods for diagnosing any disease associated with a IL-1 inflammatory haplotype. As defined in '142, diseases associated with a IL-1 inflammatory haplotype are inclusive of preterm labor and low birth weight. that the inflammatory disease may be low birth weight or adverse pregnancy outcome.

RESPONSE TO ARGUMENTS:

In the response of Paper No. 12, Applicants request that the rejection be held in abeyance until allowable subject matter has been indicated. However, it is not the Office's policy to hold rejections in abeyance. The rejection is maintained for the reasons stated above and is made final.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS:

5. The amendment filed October 4, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification as originally filed did not contemplate incorporating by reference the subject matter of applications PCT/US99/08794, 60/082, 487 and 09/345,217. While the specification as originally filed claimed priority to PCT/US99/08794 and 60/082, 487, this does not provide basis for the concept of incorporating these complete applications into the present application. As stated in MPEP 2163.07, "a claim for priority is simply a claim for the benefit of an earlier filing date for subject matter that is common to two or more applications, and does not serve to incorporate the content of the priority document in the application in which the claim for priority is made" Additionally, the present application as originally filed did not refer to or incorporate by reference the subject matter of 09/345,217.As stated in MPEP 2163.07, "a claim for priority is simply a claim for the benefit of an earlier filing date for subject matter that is common to two or more applications, and does not serve to incorporate the content of the priority document in the application in which the claim for priority is made"

Applicant is required to cancel the new matter in the reply to this Office Action.

6. Claims 1-8 and 80-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for the concept of detecting alleles 33221461 haplotype in linkage disequilibruim IL-1A (+4845) allele 2 or any allele of the 44112332 haplotype in linkage disequilibrium with IL-1B (-511) allele 2 as indicative of an adverse pregnancy outcome or as a means of identifying an allele associated with low birth weight. The specification (page 34) as originally filed teaches the alleles of the 33221461 haplotype. However, the specification does not indicate that these alleles are in linkage disequilibrium with IL-1A (+4845) allele 2 and does not contemplate detecting alleles of the 33221461 haplotype in linkage disequilibrium with IL-1A (+4845) allele 2 as indicative of an adverse pregnancy outcome or as a means of identifying an allele associated with low birth weight. Further, the specification (pages 34-35) discusses the 44112332 haplotype and the fact that alleles in this haplotype are in linkage disequilibrium with IL-1RN (+2018). However, the specification does not teaches that alleles of the 44112332 haplotype are in linkage disequilibrium with IL-1B (-511) allele 2 and does not contemplate detecting alleles of the 44112332 haplotype in linkage disequilibrium with IL-1B (-511) allele 2 as indicative of an adverse pregnancy outcome or as a means of identifying an allele associated with low birth weight. It is noted that the response of October 4, 2002 indicates that PCT/US99/08794 and

PCT/GB98/01481. However, these applications and this particular subject matter from these applications were not incorporated by reference in the originally filed specification. Additionally, it is improper to incorporate by reference essential subject matter by reference to a foreign application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

December 17, 2002

CARLA J. MYERS
PRIMARY EXAMINER